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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, UTAH, VIRGINIA, WASHINGTON, WISCONSIN, AND THE DISTRICT OF COLUMBIA EX REL. MARY BIXLER WOOD,

Plaintiffs,

v.

AVALIGN TECHNOLOGIES, INC., INSTRUMED INTERNATIONAL, INC., INSTRUMED GMBH, NEMCOMED FW, LLC, NGINSTRUMENTS, INC., ADVANTIS MEDICAL, INC., ROUNDTABLE HEALTHCARE PARTNERS, L.P., CAREFUSION CORPORATION, AND DEPUY SYNTHES, INC.,

Defendants.

COMPLAINT

UNDER SEAL

14 CIV. _____

ECF CASE

JURY TRIAL DEMANDED

Plaintiff-relator Mary Bixler Wood ("Relator"), through her attorneys, Harter Secrest & Emery LLP, alleges upon information and belief as follows:

INTRODUCTION

1. This is a suit to recover damages and penalties on behalf of the United States of America and certain States under the federal and various state False Claims Act statutes. The defendants marketed medical devices within the United States in violation of federal laws designed to assure the devices' safety and efficacy. The federal and state governments spent billions of taxpayer dollars purchasing these devices, reimbursing purchases of these devices, and reimbursing procedures using these devices. This suit seeks to hold defendants responsible for wrongfully causing this tremendous expenditure of public funds, while risking public health.

2. Relator brings this action on behalf of the United States of America (the "United States") and the States of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Utah, Washington, and Wisconsin, the Commonwealths of Massachusetts and Virginia, and the District of Columbia (collectively, the "State Plaintiffs," and, together with the United States, the "Government"), against Defendants Avalign Technologies, Inc. ("Avalign"), Instrumed International, Inc. and Instrumed GmbH (together, "Instrumed"), Nemcomed FW, LLC ("Nemcomed"), NGInstruments, Inc. ("NGI"), Advantis Medical, Inc. ("Advantis"), RoundTable Healthcare Partners, L.P. ("RoundTable"), CareFusion Corporation ("CareFusion"), and DePuy Synthes, Inc. ("DePuy") (collectively, "Defendants").

3. Defendants elevated profits over safety and ignored laws designed to protect the public from dangerous or unreliable medical devices. As a result, over the last decade, millions of illegal medical devices were sold in the United States, and a large number of those devices, along with millions of procedures using those devices, were paid for by federal healthcare programs, like Medicare, TRICARE, and CHAMPVA, as well as the Medicaid program jointly administered by the federal government and the States. Federal and state entities also, upon information and belief, directly purchased these illegal devices. The Government thus unwittingly bankrolled risky surgeries and other procedures in violation of the Government's own payment terms.

4. As set forth below, Defendants committed egregious and deliberate violations of the Federal Food, Drug and Cosmetic Act ("FDCA") and implementing regulations of the United States Food and Drug Administration ("FDA") (collectively "FDA law"). The public safety laws Defendants violated include critical laws requiring manufacturers to obtain marketing clearance from FDA before commercially distributing devices and mandating that manufacturers comply with current good manufacturing practices ("cGMP") for medical devices, among other laws. By violating these laws, Defendants caused the introduction of illegal adulterated and/or misbranded devices into the United States, creating massive potential public health risk. These violations of FDA law triggered violations of the reimbursement rules of Government healthcare programs and the conditions of Government purchasers.

5. Relator brings this action seeking damages and penalties on behalf of the Government under the False Claims Act, 31 U.S.C. §§ 3729-3733, and analogous state statutes.

JURISDICTION AND VENUE

6. This Court has jurisdiction pursuant to 31 U.S.C. § 3730 and 28 U.S.C. §§ 1331 and 1345.

7. Venue is proper in the Southern District of New York pursuant to 31 U.S.C. § 3732(a) because, upon information and belief, various Defendants transact business in this District. Furthermore, upon information and belief, a number of acts proscribed by 31 U.S.C. § 3729 occurred in this judicial district. Upon information and belief, Defendants are likewise subject to personal jurisdiction in this judicial district.

PARTIES

8. Plaintiffs are the United States and the State Plaintiffs.

9. Relator Mary Bixler Wood served as the Vice President of Quality and Regulatory Affairs for Avalign from February 2010 until Avalign terminated her in July 2013. Prior to working at Avalign, Relator had worked for Advantis, an Avalign subsidiary, from January 2009 through January 2010 as the Director of Quality and Regulatory Affairs.

10. Defendant Avalign Technologies, Inc. is a Delaware corporation with its principal place of business in Lake Forest, Illinois. It markets itself as "the premier, full-service supplier of implants, instruments, cutting tools, German Specialty instruments and cases and trays for medical device OEMs." It is a wholly owned subsidiary of RoundTable Healthcare Partners, L.P., and is the sole owner of defendants Instrumed International, Inc., Nemcomed FW, LLC, NGInstruments, Inc., and Advantis Medical, Inc.

11. Defendant Instrumed International, Inc. is a Delaware corporation with its principal place of business in Schaumburg, Illinois, and a manufacturing site in Tuttlingen, Germany. It markets itself as a manufacturer of "the highest quality, broadest line of German,

hand-held, reusable surgical instruments available," with "an inventory of over 18,000 unique, off-the-shelf product codes."

12. Defendant Instrumed GmbH is a German limited liability company with its principal place of business in Tuttlingen, Germany. It is a wholly owned subsidiary of Instrumed International, Inc. Instrumed International, Inc. markets Instrumed GmbH as the "European Manufacturing & Logistics Center" of Instrumed International, Inc.

13. Defendant Nemcomed FW, LLC is an Indiana limited liability company with its principal place of business in Fort Wayne, Indiana. It markets its business as "the development and manufacturing of precision medical instruments and implants."

14. Defendant NGInstruments, Inc. is an Indiana corporation with its principal place of business in Warsaw, Indiana. It markets itself as "a leading manufacturer of high quality drills and precision instruments in the medical device marketplace," manufacturing "over 1,400 different styles of drill bits, taps and reamers."

15. Defendant Advantis Medical, Inc. is an Indiana corporation with its principal place of business in Greenwood, Indiana. It markets itself as a "design[er] and manufacture[r] [of] world-class metal and thermoformed case and tray products for the medical device community."

16. Defendant RoundTable Healthcare Partners, L.P. is a Delaware limited partnership with its principal place of business in Lake Forest, Illinois. RoundTable markets itself as a "private equity firm focused exclusively on the healthcare industry" with "1.9 billion of capital under management." RoundTable promotes itself as "actively assist[ing] our partners in developing and improving efficient operating practices in areas such as sales and marketing, manufacturing [and] quality."

17. Defendant CareFusion Corporation is a Delaware corporation with its principal place of business in San Diego, California. CareFusion markets itself as a "global corporation serving the healthcare industry with products and services that help hospitals measurably improve the safety and quality of care."

18. Defendant DePuy Synthes, Inc., is a Delaware corporation with its principal place of business in Warsaw, Indiana. DePuy markets itself as a global leader "in providing healthcare solutions in orthopaedics, spinal care, sports medicine and neurosciences."

BACKGROUND

I. FDA RULES GOVERNING MEDICAL DEVICES

19. The Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, governs, among other things, the manufacturing and marketing of medical devices within the United States, requiring that medical devices possess a reasonable assurance of safety and effectiveness for their intended uses. The FDA regulates medical devices under the FDCA to protect consumers from medical devices that are unsafe or ineffective.

20. To protect public health, the FDCA prohibits, among other things, the marketing of many medical devices without the requisite FDA marketing clearance; *see* 21 U.S.C. § 331(p), and the adulteration or misbranding of medical devices in interstate commerce, 21 U.S.C. § 331(b). The FDCA also prohibits the introduction or delivery for introduction into interstate commerce of any adulterated or misbranded medical device, 21 U.S.C. § 331(a), the receipt in interstate commerce of any adulterated or misbranded medical device, and the delivery or proffered delivery thereof for pay or otherwise, 21 U.S.C. § 331(c), as well as the failure to comply with certain post-marketing reporting obligations, *see* 21 U.S.C. § 331(q).

A. FDA Clearance of Medical Devices Under Section 510(k)

21. Federal law grants FDA the power and responsibility to monitor medical devices intended to be marketed within the United States to ensure that the devices are reasonably safe and effective.

22. Among other things, federal law requires medical device manufactures to obtain FDA marketing clearance before certain medical devices may be commercially distributed within the United States. The purpose of this clearance process is to provide reasonable assurances of the safety and efficacy of medical devices.

23. Federal law classifies medical devices into three classes of increasing regulatory scrutiny based on the nature of the devices: Classes I, II, and III. In general, medical device manufacturers must obtain FDA marketing clearance before commercially distributing most Class II devices, as well as some Class I and Class III devices, within the United States. The marketing clearance process is generally referred to as the 510(k) clearance process, because the process is dictated by Section 510(k) of the FDCA.

24. Federal law requires 510(k) clearance in a number of circumstances. In particular, a manufacturer must seek 510(k) clearance from FDA before introducing a relevant device into interstate commerce for the first time; before marketing a change or modification to an already cleared device that "could significantly affect safety or effectiveness;" or before marketing a major change or modification to the intended use of a previously 510(k)-cleared device. *See* 21 C.F.R. § 807.81(a); *see also,* 21 U.S.C. § 360(k).

25. A device that requires 510(k) clearance may not be legally marketed in the United States until the applicant receives a clearance order from FDA.

26. By ignoring the 510(k) clearance requirement, a manufacturer deprives FDA of the ability to assess whether a device has a reasonable assurance of safety and efficacy.

27. Any device requiring, but lacking, 510(k) clearance is both adulterated and misbranded, and marketing such a device is also a prohibited act under federal law. *See* 21 U.S.C. §§ 331(p), 351(f), 352(o).

B. FDA's Quality System Regulations Ensure Compliance with Current Good Manufacturing Practices

28. Federal law requires medical device manufacturers to design, produce, package, label, evaluate, and monitor devices in accordance with current good manufacturing practices ("cGMP") to ensure that the medical devices are reasonably safe and effective.

29. These cGMP requirements for devices marketed in the United States are codified in FDA's Quality System Regulation ("QSR"). *See* 21 C.F.R. Part 820.

30. The QSR generally governs any entity that designs, manufactures, fabricates, assembles, or processes a finished device (*i.e.*, a device that is capable of functioning, whether or not it has been packaged, labeled, or sterilized), as well as any entity that performs the functions of contract sterilization, installation, relabeling, remanufacturing, repacking, or specification development, and initial distributors of foreign entities performing these functions. 21 U.S.C. § 820.3(o).

31. QSR requirements include rules, among others, governing design controls, purchasing controls, production and process controls, process validation, document controls, acceptance activity controls, nonconforming product controls, device master records, complaint handling procedures, processes for corrective and preventive actions ("CAPA"), the establishment of quality plans, procedures for and the conduct of quality audits, and document controls.

32. A medical device that is not manufactured in conformance with the applicable QSR provisions cannot be legally marketed in the United States.

33. By ignoring applicable QSR requirements, a manufacturer produces medical devices lacking a reasonable assurance of safety and efficacy.

34. Any device manufactured in violation of the applicable QSR requirements is adulterated under the FDCA. *See* 21 U.S.C. § 351(h).

C. Medical Device Reporting (MDR)

35. Federal law requires medical device manufacturers, importers, and others to report certain device-related death, serious injury, and/or malfunction events to FDA so that FDA and the public may monitor whether the medical devices present undue safety risks.

36. In particular, manufacturers and importers of medical devices and others are required to comply with FDA's medical device reporting regulation. *See generally* 21 C.F.R. Part 803.

37. In general, manufacturers must report to FDA, within thirty days, any information that "reasonably suggests that a device may have caused or contributed to a death or serious injury" or "reasonably suggests a device has malfunctioned and that this device or a similar device [that the manufacturer markets] would be likely to cause or contribute to a death or serious injury if the malfunction were to recur." 21 C.F.R. § 803.20(b)(3).

38. Manufacturers, importers, and others must establish and maintain MDR event files. 21 C.F.R. § 803.18(b)(1). MDR event files are written or electronic files containing or referencing the location of information related to any adverse event, including all documentation of deliberations and decision-making processes used to determine if a device-related death, serious injury, or malfunction was or was not reportable. 21 C.F.R. § 803.18(b)(1)(i). MDR

event files must include copies of MDR forms as required and other information related to the event. 21 C.F.R. § 803.18(b)(1)(ii).

39. To facilitate the above requirements, manufacturers, importers, and others must develop, maintain and implement written MDR procedures that provide for timely and efficient identification, communication and evaluation of events, a standardized review process, timely transmission of complete medical device reports, and documentation and recordkeeping requirements. 21 C.F.R. § 803.18(a) and (b).

40. By ignoring the MDR requirements, a manufacturer or importer may hide medical device safety risks from FDA and the public.

41. Failure to report MDRs for a device renders the device misbranded and is also a prohibited act under the FDCA. 21 U.S.C. §§ 331(q), 352(t).

D. Medical Device Labeling

42. Federal law governs the content, format, truthfulness, and completeness of medical device labeling to ensure that medical device users are not deceived and to protect the public from unsafe or ineffective device use and against safety and efficacy problems arising from, among other things, the inadvertent misuse or overuse of such devices.

43. Any medical device offered for commercialization in the United States must comply with applicable device format, content, and related labeling requirements. *See generally* 21 C.F.R. Part 801.

44. Federal law also prohibits medical device labeling from being false or misleading in any particular. 21 U.S.C. § 352(a); *see generally* 21 C.F.R., Part 801.

45. In addition, medical devices must include sufficient information for use, including adequate instructions regarding how to use devices (*e.g.*, information explaining how to clean or

sterilize devices when relevant for initial use or reuse, and information about the shelf life or the reusable life of devices when relevant), as well as adequate warnings relevant to device use. 21 U.S.C. § 352(f).

46. By ignoring labeling requirements, a manufacturer may deceive or mislead users and may cause the unsafe or ineffective use, misuse, or overuse of a medical device, rendering the device neither reasonably safe nor effective.

47. A manufacturer's violation of FDA labeling requirements renders a device misbranded under the FDCA. *See* 21 U.S.C. § 352; 21 C.F.R., Part 801.

II. GOVERNMENT PAYMENT RULES

48. Compliance with the FDA laws set forth above is essential for any reasonable assurance of the safety and efficacy of medical devices. In particular, the failure to obtain required 510(k) marketing clearance from FDA for medical devices or other adulteration or misbranding of medical devices leaves the public without reasonable assurances that such devices are safe or effective.

49. None of the major federal healthcare programs (*e.g.,* Medicare, Medicaid, TRICARE, or CHAMPVA) provides for reimbursement for the purchase or use of medical devices that lack required 510(k) clearance or are otherwise adulterated or misbranded.

50. In addition, the payment terms of federal and state funded health providers do not permit their purchase of devices that lack required 510(k) clearance or are otherwise adulterated or misbranded.

A. Medicare

51. Medicare is a federally administered health insurance program for persons over 65 and the disabled, codified as Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq.*

The Medicare program is funded by the federal government and administered by the Centers for Medicare and Medicaid Services ("CMS") within the Department of Health and Human Services.

52. Medicare rules govern the reimbursement for medical devices and reimbursement for procedures using medical devices.

53. Medicare rules prohibit reimbursement for the use of a device that is adulterated or misbranded. For instance, Medicare rules preclude payment for any device or procedure that is not "reasonable and necessary" for the treatment of illness or injury. *See, e.g.*, 42 U.S.C. § 1395y(a)(1)(A). The use of an adulterated or misbranded device is neither reasonable nor necessary for the treatment of illness or injury because, among other reasons, there are not reasonable assurances that such devices are safe or effective.

54. Medicare rules also prohibit reimbursement for the use of a device requiring, but lacking, 510(k) clearance by FDA. For instance, Medicare classifies any medical device that is neither cleared nor approved for marketing by FDA as "investigational." *See* 42 C.F.R. § 411.15(o). Federal law prohibits Medicare reimbursements "for any expenses incurred for items or services" relating to care and services using investigational devices, except for certain clinical trials. *See* 42 U.S.C. § 1395y(a)(1)(D); *see also* 42 C.F.R. § 411.15(o).

55. For these and other reasons, Medicare rules prohibit providers from seeking reimbursement for the use of devices that lack required 510(k) clearance or are otherwise adulterated or misbranded.

B. Medicaid

56. Medicaid is a health insurance program for low income individuals jointly administered by CMS and the States. Medicaid is codified at Title XIX of the Social Security Act, 42 U.S.C. § 1396 et seq., and in various provisions of state law.

57. The Medicaid program is jointly funded by the federal government and the States, and the States are required to design State Plans to fund and administer their Medicaid programs. *See* 42 U.S.C. § 1396a.

58. Federal and state Medicaid rules and regulations provide that only reasonable and necessary medical treatment is eligible for reimbursement.

59. In addition, certain state Medicaid regulations require compliance with federal laws, which includes FDA law.

60. For these and other reasons, Federal and state Medicaid rules and regulations prohibit providers from seeking reimbursement for the use of devices that lack required 510(k) clearance or are otherwise adulterated or misbranded.

C. TRICARE

61. TRICARE, formerly known as CHAMPUS, is a healthcare program administered by the United States Department of Defense that provides health insurance coverage to active-duty and retired military personnel and their dependents. *See* 10 U.S.C. § 1071, et seq.

62. TRICARE rules govern the reimbursement for medical devices and reimbursement for procedures using medical devices.

63. TRICARE rules prohibit reimbursement for the use of a device that is adulterated or misbranded. For instance, TRICARE rules preclude reimbursement for any device or procedure that is not medically necessary for the treatment of illness or injury. *See, e.g.*, 32

C.F.R. § 199.4(a)(1)(i). The use of an adulterated or misbranded device is not medically necessary for the treatment of illness or injury because, among other reasons, there are not reasonable assurances that such devices are safe or effective.

64. TRICARE rules also prohibit reimbursement for the use of a device requiring, but lacking, 510(k) clearance by FDA. For instance, TRICARE classifies any medical devices that are neither cleared nor approved for marketing by FDA as unproven and investigational. *See* 32 C.F.R. § 199.4(g)(15); TRICARE Policy Manual (2008), Chap. 8, § 5.1. Except in certain clinical trials, TRICARE rules prohibit payment for any "device, medical treatment or procedure" relating to a device or the use of a device that is unproven, including "all services directly related to the unproven . . . device." *See* 32 C.F.R. § 199.4(g)(15); TRICARE Policy Manual (2008), Chap. 8, § 5.11.

65. For these and other reasons, TRICARE rules prohibit providers from seeking reimbursement for the use of devices that lack required 510(k) clearance or are otherwise adulterated or misbranded.

D. CHAMPVA

66. CHAMPVA is a healthcare program administered by the United States Department of Veterans Affairs. The program benefits spouses and children of certain veterans. *See* 38 U.S.C. § 1781; 38 C.F.R. § 17.270, *et seq.*

67. CHAMPVA rules govern the reimbursement for medical devices and reimbursement for procedures using medical devices.

68. CHAMPVA rules prohibit reimbursement for the use of a device that is adulterated or misbranded. For instance, CHAMPVA rules preclude payment for devices or procedures that are not medically necessary. *See* 38 C.F.R. § 17.720(a). The use of an

adulterated or misbranded device is not medically necessary for the treatment of illness or injury because, among other reasons, there are not reasonable assurances that such devices are safe or effective.

69. CHAMPVA rules also prohibit reimbursement for the use of a device requiring, but lacking, 510(k) clearance by FDA. For instance, CHAMPVA limits reimbursement to the use of medical devices that have been approved or cleared by FDA. *See* CHAMPVA Policy Manual, Ch. 2, § 17.8.

70. For these and other reasons, CHAMPVA rules prohibit providers from seeking reimbursement for the use of devices that lack required 510(k) clearance or are otherwise adulterated or misbranded.

E. Federal and State Purchasers of Medical Devices

71. On information and belief, federal and state procurement policies and contracts require that purchased devices comply with FDA law, including that such devices are cleared when required under 510(k) and are not otherwise adulterated or misbranded.

72. For instance, the Veterans Administration (the "VA") has express terms stating that it will not purchase medical devices lacking the required 510(k) clearance or premarket approval, and requiring that any device sold to the VA be fully compliant with FDA law, including the QSR.

III. FDA VIOLATIONS BY THE AVALIGN COMPANIES

A. The Avalign Business Model

73. Avalign is a parent organization that operates through four subsidiary medical device companies: Instrumed, Nemcomed, NGI, and Advantis (collectively, "the Avalign Companies").

74. The Avalign Companies primarily manufacture (and at times private label) medical devices for other medical device companies.

75. For some medical device company customers, the Avalign Companies manufacture finished devices according to design specifications developed by the Avalign Companies. The Avalign Companies sometimes directly ship these products to purchasers on behalf of the Avalign Companies' medical device company customers. At other times, the Avalign Companies ship these products to the medical device company customers, and those customers distribute the products.

76. For other medical device company customers, the Avalign Companies contract-manufacture finished devices according to specifications developed by the medical device company customers.

77. The Avalign Companies have marketed themselves to medical device company customers based on claims that the Avalign Companies could design, source, and/or manufacture medical devices at lower costs and with greater speed than the medical device company customers could do themselves.

78. As alleged below, the Avalign Companies have lowered the costs, and increased the speed, of their design, sourcing, and manufacturing of medical devices for customers by ignoring and violating FDA laws relating to the safety and efficacy of medical devices.

79. These shortcuts have created substantial public health risks.

80. As alleged below, the Avalign Companies manufactured and marketed devices illegally without required 510(k) marketing clearance; in violation of QSR design control requirements; in violation of QSR purchasing control requirements; in violation of QSR production, processing, acceptance, release, device record-keeping and nonconforming product

requirements; with false and inadequate labeling; in violation of QSR complaint handling and CAPA requirements; without required reporting of MDRs about device-related injuries and malfunctions; and otherwise in violation of QSR requirements.

B. Illegal Marketing of Products Without Required FDA 510(k) Clearance

81. Over the course of at least the last decade, the Avalign Companies have illegally marketed and distributed medical devices into the United States, and caused their customers to market and distribute many such devices, without the necessary FDA premarket notification (510(k)) clearance.

82. There is an exception to the 510(k) premarket clearance requirement for so-called "preamendment devices." A preamendment device is one that was sold in interstate commerce and labeled, promoted, and distributed for a specific intended use, prior to May 28, 1976. FDA requires proof of preamendment status. Such preamendment status may be established through documentary evidence of commercial distribution prior to May 28, 1976 (*i.e.*, through copies of advertisements, journal articles, shipping documents, etc.), by sworn statements of device users with sworn statements of company employees, or by some combination thereof.

83. FDA law also requires additional 510(k) clearance before marketing any modified 510(k) cleared or preamendment device that, compared with the original 510(k) cleared or preamendment device, has been significantly changed in a way that could significantly affect its safety or efficacy or is being marketed for a new indication or use. *See* 21 C.F.R. § 807.81(a)(3).

84. The Avalign Companies illegally marketed or caused others to market thousands of different types of medical devices where the Avalign Companies knew or recklessly disregarded the fact that the devices lacked required 510(k) clearance from FDA.

1. Instrumed's Failure to Obtain 510(k) Clearance

85. Instrumed marketed medical devices for distribution into the United States, and caused its customers to distribute such devices, without the required 510(k) clearance as set forth below.

a. Devices Lacking a Legal Basis for Marketing

86. Upon information and belief, Instrumed lacked a documented basis for the legal marketing, under FDA law, of most of its devices. Internal company records, which were used to document the FDA legal basis for distribution of Instrumed devices in the United States, lacked even a purported basis for approximately two thirds of Instrumed's approximately 30,000 finished devices and components.

b. Devices Falsely Linked to 510(k) Clearances

87. Upon information and belief, Instrumed falsely claimed that a significant number of devices were covered by 510(k) clearances that did not, in fact, support those devices. For instance, upon information and belief, Instrumed internal company records falsely and implausibly claimed that a total of twelve 510(k) clearances supported a total of more than 3,500 devices.

c. Devices Based on False Preamendment Claims

88. Upon information and belief, Instrumed marketed numerous devices requiring 510(k) clearance based on the false premise that the devices qualified as preamendment.

89. Defendants knew, or recklessly disregarded the fact, that these devices were not preamendment.

90. Around 2010, Instrumed began searching for the requisite evidence to establish its devices were preamendment, such as documentary evidence. Instrumed was unable to locate any

such evidence. Nevertheless, Instrumed falsely claimed, and continues to claim, preamendment status for these sham preamendment devices.

d. Unapproved Devices Following Significant Changes

91. Upon information and belief, Instrumed marketed multiple devices that had been significantly changed, in design or in intended use, from 510(k)-cleared or preamendment versions.

92. Each of these devices required additional 510(k) clearance based on substantial changes in the design or intended use of the devices.

93. None of these devices had additional 510(k) clearance.

94. Instrumed, Avalign and RoundTable knew, or recklessly disregarded the fact that these devices did not have additional 510(k) clearance as required.

95. As a result of these actions, Defendants marketed or caused others to market numerous medical devices in the United States that had never been 510(k) cleared for marketing by FDA as reasonably safe and effective, as required by federal law.

2. Advantis's Failure to Obtain 510(k) Clearance

96. SteriPack is Advantis's primary medical device product. It is a device used for sterilizing other medical devices.

97. FDA provided Advantis or its predecessor with 510(k) clearance for a SteriPack product made with stainless steel for use in sterilizing dental instruments.

98. However, Advantis redesigned additional line extensions of the SteriPack product using aluminum and other materials and marketed devices for sterilizing orthopedic and other non-dental devices.

99. The change to include aluminum and other materials, and the change in use from dental to non-dental, required 510(k) clearance.

100. Defendants Avalign and Advantis knew, or recklessly disregarded the fact, that these devices required additional 510(k) clearance and that FDA had not cleared the devices. For instance, for many years, Advantis marketed SteriPack devices without applying for additional 510(k) clearance. Around 2010, Advantis applied for 510(k) clearance from the FDA for the significant changes in the device and its intended use. The FDA did not grant 510(k) clearance. Nevertheless, Defendants Avalign and Advantis continued to market the revised devices.

101. As a result of these actions, Defendants marketed or caused others to market SteriPack devices in the United States without 510(k) clearance for marketing from FDA as reasonably safe and effective, as required by federal law.

C. Adulteration Through Lack of Required Design Controls

102. Over the course of at least the last decade, the Avalign Companies illegally marketed medical devices for distribution into the United States, and caused their customers to market such devices, without implementing design controls required by the QSR.

103. Design controls are the checks and balances incorporated into the device design and development process. Design controls establish essential quality requirements, such as the safety, performance, and dependability of a product. The controls apply to all Class II and III devices, as well as some Class I devices. 21 C.F.R. § 820.30(a)(1).

104. The Avalign Companies repeatedly failed to implement, and/or document, the design controls meant to ensure the safety and effectiveness of their medical devices subject to design controls.

105. Design control activities must be documented in design history files.

106. Yet, the Avalign Companies did not maintain design history files for many devices subject to design controls.

107. Defendants knew, or recklessly disregarded the fact, that the Avalign Companies did not maintain design history files for many devices subject to design controls, as required by federal law. Relator repeatedly informed the Avalign Companies about their failure to maintain design history files.

108. The Avalign Companies also failed to implement other basic design controls.

109. Instrumed, for instance, had virtually no system for satisfying design control requirements. Moreover, the Avalign Companies never validated that their devices were designed in a manner by which their accompanying cleaning and sterilization instructions for use would be effective in cleaning and sterilizing the devices.

110. Defendants knew, or recklessly disregarded the fact, that the Avalign Companies failed to implement basic design controls for many devices, subject to design controls, as required by federal law. For instance, Relator informed the Avalign Companies that basic design controls were often completely lacking for certain devices and that the Avalign Companies had never validated instructions for cleaning and sterilizing the devices, as required by FDA law. The Avalign Companies used these instructions for nearly all of their devices.

111. As a result of these actions, the Avalign Companies marketed and caused their customers to market thousands of medical devices in the United States that lacked the design controls required by FDA to reasonably assure the safety and efficacy of the devices.

D. Adulteration Through Lack of Required Purchasing Controls

112. Over the course of at least the last decade, the Avalign Companies illegally marketed medical devices for distribution into the United States, and caused their customers to market such devices, without implementing purchasing controls required by the QSR.

113. Purchasing controls mandate that device manufacturers select only those suppliers, contractors, and consultants who have the capability to provide quality products and services. Final Rule, 61 Fed. Reg. 52602, 52624 (Oct. 7, 1996).

114. Purchasing controls require manufacturers to, among other things, establish product and quality specifications and requirements for their suppliers and to evaluate their suppliers and document that evaluation. *See* 21 C.F.R. § 820.50(b). In addition, manufacturers must periodically review their suppliers "at intervals consistent with the significance of the product or service provided, and the review should demonstrate conformance to specified requirements." 61 Fed. Reg. at 52624. This is often accomplished through annual audits. These basic controls are meant to "provide a greater degree of assurance, beyond that provided by receiving inspection and test, that the products received meet the finished device manufacturer's [or specification developer's] requirements." *Id.*

115. The Avalign Companies illegally marketed or caused others to market thousands of medical devices that the Avalign Companies knew were manufactured or sourced without purchasing controls as required by the QSR.

1. Instrumed's Failure to Implement Purchasing Controls

116. Instrumed outsources manufacturing of approximately 90% of its products among hundreds of different suppliers.

117. Yet, Instrumed lacks anything resembling purchasing controls.

118. For instance, Instrumed did not establish product or quality specifications or requirements. With few exceptions, none of Instrumed's suppliers had any contractual or otherwise documented arrangements specifying Instrumed's product or quality specifications or requirements. Instrumed never established, defined, or communicated specified requirements to suppliers, including quality requirements. *See* 21 C.F.R. § 820.50(a) ("Each manufacturer shall establish and maintain the requirements, including quality requirements, that must be met by suppliers").

119. Nor did Instrumed ever evaluate its suppliers as required. With few exceptions, Instrumed never audited or inspected its suppliers, never required third-party assessments, and never required objective data from the suppliers that could be used to evaluate the capabilities of the suppliers. Instrumed's suppliers also lacked quality controls of their own.

120. In place of actual supplier evaluations, Instrumed used a one-page "approval form" for each supplier, stating the conclusion that the supplier was approved. The forms were unsupported by any evidence of a quality evaluation of the suppliers. Upon information and belief, no quality personnel were even involved in the supplier "approval" process.

121. The Avalign Companies knew, or recklessly disregarded the fact, that Instrumed failed to implement key requirements under the QSR, including purchasing controls for its devices, as required by federal law. For instance, in 2012, Instrumed's President declared that a quality system was not necessary for Instrumed and would hurt the Instrumed business. As another example, Instrumed continued to use a key supplier, K2, even after Relator reported that K2 suffered from across-the-board quality control failures and even after Relator disqualified K2 as an Instrumed approved supplier. Yet, Instrumed continued to market devices produced without purchasing controls.

122. As a result of these actions, the Avalign Companies marketed and caused their customers to market thousands of medical devices in the United States that lacked the purchasing controls required by FDA to reasonably assure the safety and efficacy of the devices.

2. Advantis's Failure to Implement Purchasing Controls

123. Advantis failed to implement purchasing controls over its suppliers and contractors, including those providing welding, passivation, and anodizing services.

124. The Avalign Companies knew, or recklessly disregarded the fact, that Advantis failed to implement purchasing controls over its suppliers and contractors, as required by federal law. For instance, Relator reported that Advantis failed to implement purchasing controls over its suppliers and contractors, including those providing welding, passivation, and anodizing services. Yet, the Avalign Companies continued to market devices produced without purchasing controls.

125. As a result of these actions, the Avalign Companies marketed and caused their customers to market medical devices in the United States that lacked the purchasing controls required by FDA to reasonably assure the safety and efficacy of the devices.

E. Adulteration Through Lack of Compliance with Production Phase cGMPs

126. Over the course of at least the last decade, the Avalign Companies illegally marketed medical devices for distribution into the United States, and caused their customers to market such devices, without implementing production-related controls required by the QSR.

127. The Avalign Companies illegally marketed or caused others to market thousands of different types of medical devices that the Avalign Companies knew were made without production-related controls, as required by federal law.

128. Production controls are critical to ensure that each manufacturer produces devices that conform to their specifications. Production controls include, among other things, production and process changes, documented workmanship criteria and environmental controls, as well as process validations. *See* 21 C.F.R. §§ 820.70-820.75.

129. The Avalign Companies largely operated without production-related controls.

1. Lack of Work Procedures or Instructions or Workmanship Standards

130. The Avalign Companies failed to establish work procedures or instructions and workmanship standards as required by federal law.

131. For instance, Instrumed's manufacturing activities in Germany were conducted without work instructions or defined workmanship standards.

132. As another example, for much of the relevant period, Advantis and NGI also operated without written work instructions, and Nemcomed operated with limited work instructions.

2. Lack of Environmental Controls

133. The Avalign Companies failed to implement necessary environmental controls as required by federal law.

134. The Avalign Companies did not define or establish environmental controls to assure that manufacturing conditions that could have an adverse impact on product quality were understood, documented, maintained, or reviewed.

135. For instance, facilities at Instrumed, NGI, Nemcomed, and Advantis lacked any written procedures or defined requirements dictating controlled environments for the companies' manufacturing activities.

136. The Avalign Companies also lacked written procedures for key elements that could have an impact on equipment performance and materials maintenance, including temperature, humidity, clean air controls, or cleanliness, even as the companies produced devices that had to be used in sterile environments. There were no controls on manufacturing chemicals, fluids, or operator controls (*i.e.*, hand-washing requirements).

137. In addition, the Avalign Companies had obvious cleanliness issues, such as dust, spider webs, and exposure to outside elements.

3. Failure to Validate Processes and Properly Control Manufacturing Equipment

138. The Avalign Companies failed to validate production processes as required by federal law.

139. For instance, the Avalign Companies failed to validate sterilization processes.

140. As another example, until 2010, Instrumed, NGI, and Advantis failed to validate any of their special processes, including welding, laser etching, passivation, heat treating, anodizing, and cleaning.

141. In addition, the Avalign Companies failed to assure that equipment used in manufacturing processes met specified requirements. Prior to 2010, the Avalign Companies did not have any processes or procedures defined to assure that equipment was designed, placed, or installed correctly.

4. Lack of Acceptance Activity and Release Controls

142. Acceptance activity controls apply to products received by a manufacturer, such as contract-made finished devices or components manufactured by suppliers. 21 C.F.R. § 820.80(b). They also apply to the acceptance of in-process devices and the acceptance and release of finished devices produced by a manufacturer itself. 21 C.F.R. § 820.80(c)-(d). When

implemented, acceptance activity controls create checkpoints to test products against their specifications and remove any defective or nonconforming products.

143. Instrumed did not maintain acceptance records for receiving, in-process, or final inspection, as required by federal law.

144. Instrumed also did not establish or maintain procedures for acceptance of incoming material. For instance, Instrumed would merely do a cosmetic check of supplier products without inspecting for function, dimensions, or materials, either at acceptance from a supplier or upon release. Instrumed failed to define in-process inspection criteria during manufacturing processes or with suppliers.

5. Lack of Device Record-Keeping

145. The production-related requirements obligate manufacturers to maintain both device master records (DMRs) and device history records (DHRs), among other records. *See* 21 C.F.R. §§ 820.181 (DMR), 820.184 (DHR).

146. DMRs contain all of the instructions for manufacturing a device, including design specifications (usually taken from the design history file (DHF) described above), drawings, production methods, quality assurance procedures, acceptance criteria, and packaging and labeling specifications. *See* 21 C.F.R. § 820.181; *see also* 61 Fed. Reg. 52622.

147. DHRs include the details of a particular lot, batch, or unit, such as the date of manufacture, volume of devices, acceptance records, identification labels, and control numbers. *See* 21 C.F.R. § 820.184.

148. The Avalign Companies did not maintain DMRs or DHRs for many products, as required by federal law.

149. Advantis DMRs lacked design specifications, inspection criteria, and part numbers. The DMRs merely contained drawings.

150. Instrumed lacked most of the components of a DMR.

6. Failure to Properly Handle Nonconforming Products

151. Nonconforming products are products that fail to meet their specifications, often at the end of the production cycle.

152. The QSR requires controls for nonconforming products, including a determination of the need for an investigation into the cause, as well as procedures governing, and documentation of, any disposition of nonconforming product (including reworking the product into a saleable device). *See* 21 C.F.R. § 820.90(a)-(c).

153. The Avalign Companies regularly ignored these requirements.

154. Instrumed frequently dictated that devices be reworked, without any documentation or quality procedures.

155. CareFusion regularly sent a sales representative to visit Instrumed on a weekly basis for the reworking of problematic devices, without documentation.

156. The Avalign Companies knew, or recklessly disregarded the fact, that the Avalign Companies failed to implement production-related controls, as required by federal law. For instance, Relator reported production-related violations of the QSR to the Avalign Companies. Yet, the Avalign Companies continued to market, and caused others to market, devices made without production-related controls.

157. As a result of these actions, the Avalign Companies marketed and caused their customers to market thousands of medical devices in the United States made without production-related controls required by FDA to reasonably assure the safety and efficacy of the devices.

F. Misbranding Through False and Inadequate Labeling

158. Over the course of at least the last decade, the Avalign Companies illegally marketed medical devices with false, misleading, and/or inadequate labeling for distribution into the United States, and caused their customers to market such devices, without labeling required by law.

159. A device is misbranded if "its labeling is false or misleading in any particular." 21 U.S.C. § 352(a).

160. The Avalign Companies misbranded devices by including false and misleading information in labeling.

161. For instance, the domestic site of Instrumed in Schaumburg, Illinois permanently laser-marked certain devices as "Made in Germany," which were not made in Germany in any part. The devices were in fact made in Pakistan.

162. A device is also misbranded if its labeling does not include adequate directions for use or adequate warnings. 21 U.S.C. § 352(f).

163. Instrumed regularly violated this rule.

164. For instance, Instrumed regularly shipped products without any instructions for use ("IFUs") in the case of certain devices.

165. As another example, Instrumed removed IFUs that a supplier, Trokamed, as the 510(k)-holder of the device, provided to Instrumed. Customers using the Trokamed-made devices experienced significant problems, including patient injuries that Instrumed attributed to misuse. Yet, the users lacked the IFUs.

166. Similarly, the Avalign Companies repeatedly failed to determine and indicate the shelf life of devices where relevant in labeling.

167. The Avalign Companies generally did not include such information, even when the devices could become unsafe or ineffective after a period of use.

168. Nor did the Avalign Companies provide valid instructions on sterilization. As noted above, Instrumed used a one-size-fits-all IFU addressing sterilization with nearly all of its devices. These instructions were not validated with respect to any device. Their inclusion is both inadequate and misleading, as the instructions do not describe a validated procedure.

169. Defendants knew, or recklessly disregarded the fact, that the Avalign Companies failed to comply with FDA labeling requirements. For instance, Relator informed the Avalign Companies that their labels and/or other labeling were insufficient. Yet, the Avalign Companies continued to market the misbranded devices.

170. As a result of these actions, the Avalign Companies marketed and caused their customers to market thousands of misbranded medical devices in the United States that had false or misleading statements or that lacked accurate and complete labeling as required by FDA to reasonably assure the safety and efficacy of the devices.

G. Adulteration Through Lack of Complaint Handling Procedures and CAPA

171. Over the course of at least the last decade, the Avalign Companies illegally marketed medical devices for distribution into the United States, and caused their customers to market such devices, without proper complaint handling and CAPA, as required by the QSR to guard against product problems that could pose safety and efficacy issues for patients.

172. The QSR requires manufacturers to implement complaint handling processes, including to maintain complaint files and to conduct investigations when complaints involve the possible failure of a device, or its packaging or labeling to meet specifications or involving MDR reportable event. 21 C.F.R. §§ 820.198. In addition, manufacturers must establish procedures

for, and when appropriate conduct, corrective and preventive actions (CAPA) to address product and other quality problems. 21 C.F.R. § 820.100.

173. The Avalign Companies largely failed to investigate complaints when required and frequently ignored the key CAPA requirements.

174. None of the Avalign Companies had adequate complaint handling processes.

175. For instance, none of the companies conducted legitimate investigations into root causes of device failures, and none had any management oversight of CAPA generally.

176. Instrumed had no process for establishing CAPA where appropriate.

177. The Avalign Companies often failed to follow up with suppliers who provided components or finished devices to the Avalign Companies, when the components or finished devices were subjects of complaints.

178. CareFusion regularly sent a sales representative to visit Instrumed on a weekly basis for the reworking of problematic devices, without documentation. These returns were not treated as complaints or the failures investigated.

179. The lack of legitimate failure investigations and root cause analyses meant that devices continually failed without solutions to fix problems.

180. The Avalign Defendants knew, or recklessly disregarded the fact, that Avalign failed to implement sufficient complaint handling and CAPA processes, as required by federal law. For instance, Relator reported to Avalign that existing procedures and practices were insufficient. Relator reported to Avalign and Instrumed that Instrumed lacked, among other requirements, investigation and documentation of root causes of product problems, evidence of corrective action, and documentation of containment actions. Yet, Avalign and Instrumed continued to market devices lacking sufficient complaint handling and CAPA processes to

address actual or potential product problems which could pose safety or efficacy issues for patients.

181. As a result of these actions, the Avalign Companies marketed and caused their customers to market thousands of adulterated medical devices in the United States by virtue of noncompliant complaint handling and CAPA processes which did not reasonably assure the safety and efficacy of the devices.

H. Misbranding Through Failure to File MDRs

182. Over the course of at least the last decade, the Avalign Companies illegally marketed medical devices for distribution into the United States, and caused their customers to market such devices, without reporting MDRs, as required by federal law.

183. In general, finished device manufacturers, importers, and others are required to report certain device-related deaths, serious injuries, and/or malfunctions to FDA. For example, manufacturers must report after they became aware of information that "reasonably suggests that a device may have caused or contributed to a death or serious injury" or "reasonably suggests a device has malfunctioned and that this device or a similar device [that the manufacturer markets] would be likely to cause or contribute to a death or serious injury if the malfunction were to recur." 21 C.F.R. § 803.20(b)(3).

184. These reports are called medical device reports or MDRs.

185. Prior to 2011, Instrumed (Germany), Nemcomed and Advantis all failed to have procedures or processes defined to evaluate complaints and to file MDRs.

186. Instrumed intentionally refused to file certain MDRs.

187. Instrumed did not file MDRs, as required by federal law, following reports of, for instance, device malfunctions that could cause, for example, penile amputations, or burns to various body organs.

188. Prior to June 2011, Instrumed repeatedly failed to submit MDRs to FDA, as required, when it learned information suggesting its devices "may have caused or contributed to a death or serious injury," or "malfunctioned" and would likely "cause or contribute to a death or serious injury if the malfunction were to recur." *See* 21 C.F.R. § 803.20(b)(3).

189. The Avalign Companies knew, or recklessly disregarded the fact, that the Avalign Companies failed to report MDRs, as required by federal law. They continued to market devices for which they had wrongfully withheld MDR filings.

190. As a result of these actions, the Avalign Companies marketed and caused their customers to market thousands of misbranded medical devices in the United States by failing to file MDRs as required by FDA law to reasonably assure the safety and efficacy of the devices.

I. Adulteration Through Other QSR Violations

191. Over the course of at least the last decade, the Avalign Companies illegally marketed medical devices for distribution into the United States, and caused their customers to market such devices, in violation of other QSR requirements, beyond those described above.

192. The QSR requires manufacturers to establish quality plans defining quality practices, resources, and activities relevant to devices that are designed and manufactured by the manufacturer. *See* 21 C.F.R. § 820.20.

193. Until 2009, none of the Avalign Companies had any quality plan.

194. Until 2012, none of the Avalign Companies fully implemented a quality plan.

195. Instrumed never fully implemented a quality plan.

196. The QSR requires manufacturers to establish procedures for quality audits and to conduct audits to assure that the quality system is in compliance with the QSR. *See* 21 C.F.R. § 820.22.

197. Until 2009, none of the Avalign Companies had any procedures for conducting quality audits, as required by the QSR.

198. The QSR also requires manufacturers to provide adequate resources, including assignment of trained personnel, for management, performance of work, and assessment activities, including internal quality audits, to meet the QSR requirements. *See* 21 C.F.R. § 820.20(d).

199. None of the Avalign Companies dedicated adequate resources to meet the requirements of the QSR.

200. The QSR also requires manufacturers, where appropriate, to establish and maintain valid statistical sampling plans. *See* 21 C.F.R. § 820.250.

201. None of the Avalign Companies established valid statistical sampling plans as required by the QSR.

202. The QSR requires manufacturers to establish and maintain document procedures to control all documents required by the QSR. *See* 21 C.F.R. § 820.40.

203. None of the Avalign Companies instituted adequate document controls as required by the QSR.

204. The QSR requires manufacturers to ensure that device packaging and shipping containers are designed and constructed to protect devices from alteration or damage during processing, storage, handling, and distribution. *See* 21 C.F.R. § 820.130.

205. Instrumed, NGI, and Nemcomed failed to design and construct packaging to protect devices from alteration or damage, and none of these Defendants conducted any validation activities to assure that medical devices would not be altered or damaged in their packages.

IV. FDA VIOLATIONS BY CAREFUSION

206. CareFusion knew about many of the problems at the Avalign Companies, or recklessly disregarded the fact that the Avalign-produced devices it was distributing were non-cleared and otherwise adulterated or misbranded.

207. The Avalign Companies promised quicker and cheaper products. They cut corners to do so. CareFusion knew or should have known, from its own experiences, that the Avalign Companies were making promises that were too good to be true.

208. Indeed, CareFusion was keenly aware of gross FDA law violations by Instrumed, but looked the other way.

A. Lack of 510(k) Clearance

209. For instance, CareFusion knew that Instrumed was distributing devices without required 510(k) clearance or evidence of preamendment status.

210. For example, on December 13, 2010, CareFusion emailed a list of devices to Instrumed and identified that "I have the following products from Instrumed that have a 'Preamendment' regulatory status, but no evidence in the file to support that status."

211. CareFusion asked Instrumed , "Do you have a 510K to cover these items? If not, do you have evidence of preamendment status that we could obtain for our files?"

212. In response, Instrumed bluntly responded: "No."

213. Upon information and belief, CareFusion continued to purchase and distribute these non-cleared devices from Instrumed.

B. IFU Issues

214. As another example, CareFusion purchased and distributed medical devices from the Avalign Companies without proper instructions for use ("IFUs").

215. CareFusion frequently looked to Instrumed to assist with issues regarding gaps in its IFU documentation, while continuing to market products without the proper documentation.

216. In fact, as late as June 2013, CareFusion was packaging devices purchased from Instrumed containing obsolete IFUs.

217. CareFusion continued to market products without proper labeling while they investigated the gaps in labeling.

218. Upon information and belief, CareFusion knew of, or deliberately ignored evidence of, Avalign's systemic disregard for FDA requirements.

V. FDA VIOLATIONS BY DEPUY

219. DePuy knew about many of the problems at the Avalign Companies, or recklessly disregarded the fact that the Avalign-produced devices it was distributing were non-cleared and otherwise adulterated or misbranded.

220. The Avalign Companies promised quicker and cheaper products. They cut corners to do so. DePuy knew or should have known, from its own experiences, that the Avalign Companies were making promises that were too good to be true.

221. Indeed, DePuy was keenly aware of gross FDA law violations by Instrumed, Advantis, and NGI, but looked the other way.

A. Lack of Purchasing Controls

222. For instance, DePuy knew, or recklessly disregarded the fact that, Instrumed and NGI were distributing devices to it when Instrumed and NGI were not applying required purchasing controls to their suppliers.

223. DePuy never audited Instrumed's purchasing controls.

224. DePuy knew that NGI did not evaluate supplier capability to meet specified requirements, as required by the QSR. Yet, DePuy continued to market devices made without sufficient purchasing controls.

225. DePuy recklessly disregarded similar purchasing control failures at other Avalign Companies, including Instrumed.

B. Lack of Labeling Oversight

226. As another example, DePuy knew, or recklessly disregarded the fact that, DePuy shipped devices manufactured by Advantis and NGI with grossly insufficient labeling.

227. Advantis and NGI shipped devices to DePuy with inventory tags and identification labels, rather than FDA-compliant labeling. Advantis and NGI did not have validated processes for applying the correct tags and labels, and the tags and labels did not comply with FDA content requirements.

228. DePuy re-packaged and distributed the Advantis and NGI devices without removing the unvalidated inventory tags and identification labels and without substituting FDA-compliant labeling.

229. As a result, DePuy distributed devices lacking labeling that complied with federal law.

CONCLUSION

230. For at least the last decade, Defendants have marketed, or caused others to market, thousands of medical devices within the United States in violation of federal laws designed to assure the devices' safety and efficacy. These devices have lacked FDA clearance for marketing and have otherwise been adulterated and misbranded.

231. The FDA law violations have not been isolated, sporadic, or immaterial to public safety. Rather, the Avalign Companies have engaged in chronic, systemic, and egregious violations of FDA law. The violations have covered the spectrum of FDA regulation of medical devices, from lack of 510(k) clearance and QSR design controls, through lack of purchasing and production-related controls, to labeling, complaint handling, CAPA, MDR reporting, and other QSR violations.

232. These systemic violations pose significant risks to public health.

233. Defendants knew, or recklessly disregarded the fact, that the Avalign Companies and CareFusion and DePuy were marketing, or causing others to market, thousands of medical devices within the United States in violation of federal laws designed to assure the devices' safety and efficacy. Defendants repeatedly chose to ignore violations of FDA law and to continue marketing, or to continue causing others to market, medical devices in violation of Section 510(k) of the FDCA, the QSR, and/or other provisions of FDA law. Among other things, the Avalign Companies and RoundTable ignored Relator's repeated reports of violations of FDA law.

234. On information and belief, the federal and state governments have, unwittingly, in violation of federal and state payment rules and conditions, spent billions of taxpayer dollars on

purchasing these devices, reimbursing purchases of these devices, and reimbursing procedures using these devices.

COUNT I

Violations of the False Claims Act
(31 U.S.C. § 3729(a)(1)(A))
Presentation of False Claims

235. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

236. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the Government and/or to contractors, grantees, or other recipients of Government funds used to advance Government interests, false and fraudulent claims for payment in connection with introducing non-cleared and otherwise adulterated and/or misbranded devices into interstate commerce.

237. The Government paid claims and incurred losses, and/or contractors, grantees, or other recipients of Government funds used to advance Government interests paid claims and incurred losses, as a result of Defendants' wrongful conduct.

238. By reason of such false and/or fraudulent claims, the Government has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

COUNT II

Violations of the False Claims Act
(31 U.S.C. § 3729(a)(1)(B))
Use of False Statements

239. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

240. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, made, used, or caused to be made or used, false records and/or statements material to false or fraudulent claims to the Government and/or to contractors, grantees, or other recipients of Government funds used to advance Government interests, in connection with introducing non-cleared and otherwise adulterated and/or misbranded devices into interstate commerce.

241. The Government paid claims and incurred losses, and/or contractors, grantees, or other recipients of Government funds used to advance Government interests paid claims and incurred losses, as a result of Defendants' wrongful conduct.

242. By reason of such false and/or fraudulent claims, the Government has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

COUNT III

Violations of the False Claims Act
(31 U.S.C. § 3729(a)(1)(C))
Conspiracy

243. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

244. Defendants conspired between and among themselves to commit the violations set forth in the preceding claims.

245. The Government paid claims and incurred losses, and/or contractors, grantees, or other recipients of Government funds used to advance Government interests paid claims and incurred losses, as a result of Defendants' wrongful conduct.

246. By reason of such false and/or fraudulent claims, the Government has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

COUNT IV

Violation of the California False Claims Act (Cal. Govt. Code. § 1265 *et seq.*)

247. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

248. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the State of California and/or to contractors, grantees, or other recipients of the State of California funds used to advance the State of California's interests, false and fraudulent claims for payment in connection with introducing non-cleared and otherwise adulterated and/or misbranded devices for sale in the State of California.

249. The State of California paid claims and incurred losses, and/or contractors, grantees, or other recipients of the State of California funds used to advance the interests of the State of California paid claims and incurred losses, as a result of Defendants' wrongful conduct.

250. By reason of such false and/or fraudulent claims, the State of California has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

251. Pursuant to Cal. Govt. Code § 12651(a), the State of California is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by Defendants.

COUNT V

Violation of the
Colorado Medicaid False Claims Act
(Col. Rev. Stat. § 25.5-4-303.5 *et seq.*)

252. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

253. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the State of Colorado and/or to contractors, grantees, or other recipients of the State of Colorado funds used to advance the interests of the State of Colorado, false and fraudulent claims for payment in connection with introducing non-cleared and otherwise adulterated and/or misbranded devices for sale in the State of Colorado.

254. The State of Colorado paid claims and incurred losses, and/or contractors, grantees, or other recipients of the State of Colorado funds used to advance the interests of the State of Colorado paid claims and incurred losses, as a result of Defendants' wrongful conduct.

255. By reason of such false and/or fraudulent claims, the State of Colorado has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

256. Pursuant to Col. Rev. Stat. § 25.5-4-305, the State of Colorado is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by Defendants.

COUNT VI

Violations of Connecticut False Claims Act
For Medical Assistance Programs
(Conn. Gen. Stat. § 17b-301 *et seq.*)

257. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

258. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the State of Connecticut and/or to contractors, grantees, or other recipients of the State of Connecticut funds used to advance the interests of the State of Connecticut, false and fraudulent claims for payment in connection with introducing non-cleared and otherwise adulterated and/or misbranded devices for sale in the State of Connecticut.

259. The State of Connecticut paid claims and incurred losses, and/or contractors, grantees, or other recipients of the State of Connecticut funds used to advance the interests of the State of Connecticut paid claims and incurred losses, as a result of Defendants' wrongful conduct.

260. By reason of such false and/or fraudulent claims, the State of Connecticut has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

261. Pursuant to Conn. Gen. Stat. § 17b-301b, the State of Connecticut is entitled to three times the amount of actual damages plus the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by Defendants.

COUNT VII

Violation of the
Delaware False Claims and Reporting Act
(Del. Code. Ann. tit. 6, § 1201 *et seq.*)

262. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

263. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the State of Delaware and/or to contractors, grantees, or other recipients of the State of Delaware funds used to advance the interests of the State of Delaware, false and fraudulent claims for payment in connection with introducing non-cleared and otherwise adulterated and/or misbranded devices for sale in the State of Delaware.

264. The State of Delaware paid claims and incurred losses, and/or contractors, grantees, or other recipients of the State of Delaware funds used to advance the interests of the State of Delaware paid claims and incurred losses, as a result of Defendants' wrongful conduct.

265. By reason of such false and/or fraudulent claims, the State of Delaware has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

266. Pursuant to Del. Code Ann. tit. 6, § 1201(a), the State of Delaware is entitled to three times the amount of actual damages plus the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by Defendants.

COUNT VIII

Violation of the District of Columbia False Claims Act (D.C. Code Ann. § 2-308.03 *et seq.*)

267. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

268. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the District of Columbia and/or to contractors, grantees, or other recipients of the District of Columbia funds used to advance the interests of the District of Columbia, false and fraudulent claims for payment in connection with introducing non-cleared and otherwise adulterated and/or misbranded devices for sale in the District of Columbia.

269. The District of Columbia paid claims and incurred losses, and/or contractors, grantees, or other recipients of the District of Columbia funds used to advance the interests of the District of Columbia paid claims and incurred losses, as a result of Defendants' wrongful conduct.

270. By reason of such false and/or fraudulent claims, the District of Columbia has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

271. Pursuant to D.C. Code Ann. § 2-308.14, the District of Columbia is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by the Defendants.

COUNT IX

Violation of the Florida False Claims Act
(Fla. Stat. Ann. § 68.081 *et seq.*)

272. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

273. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the State of Florida and/or to contractors, grantees, or other recipients of the State of Florida funds used to advance the interests of the State of Florida, false and fraudulent claims for payment in connection with introducing non-cleared and otherwise adulterated and/or misbranded devices for sale in the State of Florida.

274. The State of Florida paid claims and incurred losses, and/or contractors, grantees, or other recipients of the State of Florida funds used to advance the interests of the State of Florida paid claims and incurred losses, as a result of Defendants' wrongful conduct.

275. By reason of such false and/or fraudulent claims, the State of Florida has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

276. Pursuant to Fla. Stat. Ann. § 68.082.2, the State of Florida is entitled to three times the amount of actual damages plus the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by the Defendants.

COUNT X

Violation of the Georgia False Medicaid Claims Act (Ga. Code Ann. § 49-4-168.1 *et seq.*)

277. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

278. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the State of Georgia and/or to contractors, grantees, or other recipients of the State of Georgia funds used to advance the interests of the State of Georgia, false and fraudulent claims for payment in connection with introducing non-cleared and otherwise adulterated and/or misbranded devices for sale in the State of Georgia.

279. The State of Georgia paid claims and incurred losses, and/or contractors, grantees, or other recipients of the State of Georgia funds used to advance the interests of the State of Georgia paid claims and incurred losses, as a result of Defendants' wrongful conduct.

280. By reason of such false and/or fraudulent claims, the State of Georgia has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

281. Pursuant to Ga. Code Ann. § 49-4-168.1(a), the State of Georgia is entitled to three times the amount of actual damages plus the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by the Defendants.

COUNT XI

Violation of the Hawaii False Claims Act
(Haw. Rev. Stat. § 661-21 *et seq.*)

282. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

283. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the State of Hawaii and/or to contractors, grantees, or other recipients of the State of Hawaii funds used to advance the interests of the State of Hawaii, false and fraudulent claims for payment in connection with introducing non-cleared and otherwise adulterated and/or misbranded devices for sale in the State of Hawaii.

284. The State of Hawaii paid claims and incurred losses, and/or contractors, grantees, or other recipients of the State of Hawaii funds used to advance the interests of the State of Hawaii paid claims and incurred losses, as a result of Defendants' wrongful conduct.

285. By reason of such false and/or fraudulent claims, the State of Hawaii has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

286. Pursuant to Haw. Rev. Stat. § 661-21(a), the State of Hawaii is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by the Defendants.

COUNT XII

Violation of the Illinois Whistleblower Reward and Protection Act (740 Ill. Comp. Stat. § 175/1 *et seq.*)

287. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

288. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the State of Illinois and/or to contractors, grantees, or other recipients of the State of Illinois funds used to advance the interests of the State of Illinois, false and fraudulent claims for payment in connection with introducing non-cleared and otherwise adulterated and/or misbranded devices for sale in the State of Illinois.

289. The State of Illinois paid claims and incurred losses, and/or contractors, grantees, or other recipients of the State of Illinois funds used to advance the interests of the State of Illinois paid claims and incurred losses, as a result of Defendants' wrongful conduct.

290. By reason of such false and/or fraudulent claims, the State of Illinois has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

291. Pursuant to 740 Ill. Comp. Stat. § 175/3(a), the State of Illinois is entitled to three times the amount of actual damages plus the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by the Defendants.

COUNT XIII

Violation of the Indiana False Claims and Whistleblower Protection Act (Ind. Code § 5-11-5.5-1 *et seq.*)

292. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

293. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the State of Indiana and/or to contractors, grantees, or other recipients of the State of Indiana funds used to advance the interests of the State of Indiana, false and fraudulent claims for payment in connection with introducing non-cleared and otherwise adulterated and/or misbranded devices for sale in the State of Indiana.

294. The State of Indiana paid claims and incurred losses, and/or contractors, grantees, or other recipients of the State of Indiana funds used to advance the interests of the State of Indiana paid claims and incurred losses, as a result of Defendants' wrongful conduct.

295. By reason of such false and/or fraudulent claims, the State of Indiana has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

296. Pursuant to Ind. Code § 5-11-5.5-2(b), the State of Indiana is entitled to three times the amount of actual damages plus the maximum penalty of $5,000 for each and every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by the Defendants.

COUNT XIV

Violations of Iowa False Claims Act
(Iowa Code § 685 *et seq.*)

297. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

298. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the State of Iowa and/or to contractors, grantees, or other recipients of the State of Iowa funds used to advance the interests of the State of Iowa, false and fraudulent claims for payment in connection with introducing non-cleared and otherwise adulterated and/or misbranded devices for sale in the State of Iowa.

299. The State of Iowa paid claims and incurred losses, and/or contractors, grantees, or other recipients of the State of Iowa funds used to advance the interests of the State of Iowa paid claims and incurred losses, as a result of Defendants' wrongful conduct.

300. By reason of such false and/or fraudulent claims, the State of Iowa has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

301. Pursuant to Iowa Code § 685.2, the State of Iowa is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by the Defendants.

COUNT XV

Violation of the Louisiana Medical Assistance Programs Integrity Law (La. Rev. Stat. Ann. § 46:439.1 *et seq.*)

302. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

303. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the State of Louisiana and/or to contractors, grantees, or other recipients of the State of Louisiana funds used to advance the interests of the State of Louisiana, false and fraudulent claims for payment in connection with introducing non-cleared and otherwise adulterated and/or misbranded devices for sale in the State of Louisiana.

304. The State of Louisiana paid claims and incurred losses, and/or contractors, grantees, or other recipients of the State of Louisiana funds used to advance the interests of the State of Louisiana paid claims and incurred losses, as a result of Defendants' wrongful conduct.

305. By reason of such false and/or fraudulent claims, the State of Louisiana has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

306. Pursuant to La. Rev. Stat. Ann. § 46:438.6, the State of Louisiana is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by the Defendants.

COUNT XVI

Violations of the Maryland
False Health Claims Act
(Md. Health-General Code Ann. § 2-602 *et seq.*)

307. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

308. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the State of Maryland and/or to contractors, grantees, or other recipients of the State of Maryland funds used to advance the interests of the State of Maryland, false and fraudulent claims for payment in connection with introducing non-cleared and otherwise adulterated and/or misbranded devices for sale in the State of Maryland.

309. The State of Maryland paid claims and incurred losses, and/or contractors, grantees, or other recipients of the State of Maryland funds used to advance the interests of the State of Maryland paid claims and incurred losses, as a result of Defendants' wrongful conduct.

310. By reason of such false and/or fraudulent claims, the State of Maryland has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

311. Pursuant to Md. HEALTH-GENERAL Code Ann. § 2-602(b)(i) and (ii), the State of Maryland is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by the Defendants.

COUNT XVII

Violation of the Massachusetts False Claims Law
(Mass. Gen. Law. ch. 12, § 5A *et seq.*)

312. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

313. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the Commonwealth of Massachusetts and/or to contractors, grantees, or other recipients of the Commonwealth of Massachusetts funds used to advance the interests of the Commonwealth of Massachusetts, false and fraudulent claims for payment in connection with introducing non-cleared and otherwise adulterated and/or misbranded devices for sale in the Commonwealth of Massachusetts.

314. The Commonwealth of Massachusetts paid claims and incurred losses, and/or contractors, grantees, or other recipients of the Commonwealth of Massachusetts funds used to advance the interests of the Commonwealth of Massachusetts paid claims and incurred losses, as a result of Defendants' wrongful conduct.

315. By reason of such false and/or fraudulent claims, the Commonwealth of Massachusetts has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

316. Pursuant to Mass. Gen. Law. ch. 12, § 5B, the Commonwealth of Massachusetts is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by the Defendants.

COUNT XVIII

Violation of the Michigan Medicaid False Claims Act (Mich. Comp. Laws § 400.601 *et seq.*)

317. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

318. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the State of Michigan and/or to contractors, grantees, or other recipients of the State of Michigan funds used to advance the interests of the State of Michigan, false and fraudulent claims for payment in connection with introducing non-cleared and otherwise adulterated and/or misbranded devices for sale in the State of Michigan.

319. The State of Michigan paid claims and incurred losses, and/or contractors, grantees, or other recipients of the State of Michigan funds used to advance the interests of the State of Michigan paid claims and incurred losses, as a result of Defendants' wrongful conduct.

320. By reason of such false and/or fraudulent claims, the State of Michigan has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

321. Pursuant to Mich. Comp. Laws § 400.612, the State of Michigan is entitled to a civil penalty equal to the full amount received by the person benefiting from the fraud, three times the amount of actual damages, plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement presented or caused to be presented by the Defendants.

COUNT XIX

Violations of the Minnesota False Claims Act
(Minn. Stat. § 15C.01 *et seq.*)

322. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

323. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the State of Minnesota and/or to contractors, grantees, or other recipients of the State of Minnesota funds used to advance the interests of the State of Minnesota, false and fraudulent claims for payment in connection with introducing non-cleared and otherwise adulterated and/or misbranded devices for sale in the State of Minnesota.

324. The State of Minnesota paid claims and incurred losses, and/or contractors, grantees, or other recipients of the State of Minnesota funds used to advance the interests of the State of Minnesota paid claims and incurred losses, as a result of Defendants' wrongful conduct.

325. By reason of such false and/or fraudulent claims, the State of Minnesota has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

326. Pursuant to Minn. Stat. § 15C.02(a), the State of Minnesota is entitled to three times the amount of actual damages plus the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by the Defendants.

COUNT XX

Violations of the Montana False Claims Act
(Mont. Code Ann. § 17-8-401 *et seq.*)

327. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

328. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the State of Montana and/or to contractors, grantees, or other recipients of the State of Montana funds used to advance the interests of the State of Montana, false and fraudulent claims for payment in connection with introducing non-cleared and otherwise adulterated and/or misbranded devices for sale in the State of Montana.

329. The State of Montana paid claims and incurred losses, and/or contractors, grantees, or other recipients of the State of Montana funds used to advance the interests of the State of Montana paid claims and incurred losses, as a result of Defendants' wrongful conduct.

330. By reason of such false and/or fraudulent claims, the State of Montana has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

331. Pursuant to Mont. Code Ann. § 17-8-403, the State of Montana is entitled to three times the amount of actual damages plus the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by the Defendants.

COUNT XXI

Violation of the Nevada False Claims Act
(Nev. Rev. Stat. § 357.010 *et seq.*)

332. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

333. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the State of Nevada and/or to contractors, grantees, or other recipients of the State of Nevada funds used to advance the interests of the State of Nevada, false and fraudulent claims for payment in connection with introducing non-cleared and otherwise adulterated and/or misbranded devices for sale in the State of Nevada.

334. The State of Nevada paid claims and incurred losses, and/or contractors, grantees, or other recipients of the State of Nevada funds used to advance the interests of the State of Nevada paid claims and incurred losses, as a result of Defendants' wrongful conduct.

335. By reason of such false and/or fraudulent claims, the State of Nevada has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

336. Pursuant to Nev. Rev. Stat. § 357.040(1), the State of Nevada is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by the Defendants.

COUNT XXII

Violation of the New Hampshire False Claims Act
(N.H. Rev. Stat. Ann. § 167:61-b *et seq.*)

337. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

338. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the State of New Hampshire and/or to contractors, grantees, or other recipients of the State of New Hampshire funds used to advance the interests of the State of New Hampshire, false and fraudulent claims for payment in connection with introducing non-cleared and otherwise adulterated and/or misbranded devices for sale in the State of New Hampshire.

339. The State of New Hampshire paid claims and incurred losses, and/or contractors, grantees, or other recipients of the State of New Hampshire funds used to advance the interests of the State of New Hampshire paid claims and incurred losses, as a result of Defendants' wrongful conduct.

340. By reason of such false and/or fraudulent claims, the State of New Hampshire has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

341. Pursuant to N.H. Rev. Stat. Ann. § 167:61-b, the State of New Hampshire is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by the Defendants.

COUNT XXIII

Violation of the New Jersey False Claims Act
(N.J. Stat. Ann. § 2A:32C-1 *et seq.*)

342. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

343. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the State of New Jersey and/or to contractors, grantees, or other recipients of the State of New Jersey funds used to advance the interests of the State of New Jersey, false and fraudulent claims for payment in connection with introducing non-cleared and otherwise adulterated and/or misbranded devices for sale in the State of New Jersey.

344. The State of New Jersey paid claims and incurred losses, and/or contractors, grantees, or other recipients of the State of New Jersey funds used to advance the interests of the State of New Jersey paid claims and incurred losses, as a result of Defendants' wrongful conduct.

345. By reason of such false and/or fraudulent claims, the State of New Jersey has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

346. Pursuant to N.J. Stat. Ann. § 2A:32C-3, the State of New Jersey is entitled to three times the amount of actual damages plus the maximum penalty of allowed under the federal False Claims Act, 31 U.S.C. § 3729, for each and every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by the Defendants.

COUNT XXIV

Violation of the New Mexico Medicaid False Claims Act and Fraud Against Tax Payers Act (N.M. Stat. Ann. § 27-14-1 *et seq.* and § 44-9-1 *et seq.*)

347. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

348. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the State of New Mexico and/or to contractors, grantees, or other recipients of the State of New Mexico funds used to advance the interests of the State of New Mexico, false and fraudulent claims for payment in connection with introducing non-cleared and otherwise adulterated and/or misbranded devices for sale in the State of New Mexico.

349. The State of New Mexico paid claims and incurred losses, and/or contractors, grantees, or other recipients of the State of New Mexico funds used to advance the interests of the State of New Mexico paid claims and incurred losses, as a result of Defendants' wrongful conduct.

350. By reason of such false and/or fraudulent claims, the State of New Mexico has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

351. Pursuant to N.M. Stat. Ann. § 27-14-4 and § 44-9-3, the State of New Mexico is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by the Defendants.

COUNT XXV

Violation of the New York False Claims Act
(N.Y. State Fin. Law § 187 *et seq.*)

352. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

353. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the State of New York and/or to contractors, grantees, or other recipients of the State of New York funds used to advance the interests of the State of New York, false and fraudulent claims for payment in connection with introducing non-cleared and otherwise adulterated and/or misbranded devices for sale in the State of New York.

354. The State of New York paid claims and incurred losses, and/or contractors, grantees, or other recipients of the State of New York funds used to advance the interests of the State of New York paid claims and incurred losses, as a result of Defendants' wrongful conduct.

355. By reason of such false and/or fraudulent claims, the State of New York has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

356. Pursuant to N.Y. State Fin. Law § 189.1(g), the State of New York is entitled to three times the amount of actual damages plus the maximum penalty of $12,000 for each and every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by the Defendants.

COUNT XXVI

Violations of the North Carolina False Claims Act
(N.C. Gen. Stat. § 1-605 *et seq.*)

357. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

358. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the State of North Carolina and/or to contractors, grantees, or other recipients of the State of North Carolina funds used to advance the interests of the State of North Carolina, false and fraudulent claims for payment in connection with introducing non-cleared and otherwise adulterated and/or misbranded devices for sale in the State of North Carolina.

359. The State of North Carolina paid claims and incurred losses, and/or contractors, grantees, or other recipients of the State of North Carolina funds used to advance the interests of the State of North Carolina paid claims and incurred losses, as a result of Defendants' wrongful conduct.

360. By reason of such false and/or fraudulent claims, the State of North Carolina has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

361. Pursuant to N.C. Gen. Stat. § 1-607(a), the State of North Carolina is entitled to three times the amount of actual damages plus the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by the Defendants.

COUNT XXVII

Violation of the Oklahoma Medicaid False Claims Act
(63 Okla. St. Ann. § 5053 *et seq.*)

362. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

363. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the State of Oklahoma and/or to contractors, grantees, or other recipients of the State of Oklahoma funds used to advance the interests of the State of Oklahoma, false and fraudulent claims for payment in connection with introducing non-cleared and otherwise adulterated and/or misbranded devices for sale in the State of Oklahoma.

364. The State of Oklahoma paid claims and incurred losses, and/or contractors, grantees, or other recipients of the State of Oklahoma funds used to advance the interests of the State of Oklahoma paid claims and incurred losses, as a result of Defendants' wrongful conduct.

365. By reason of such false and/or fraudulent claims, the State of Oklahoma has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

366. Pursuant to 63 Okla. St. Ann. § 5053.1(B), the State of Oklahoma is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by the Defendants.

COUNT XXIII

Violation of the State False Claims Act (Rhode Island)
(R.I. Gen. Laws § 9-1.1-1 *et seq.*)

367. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

368. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the State of Rhode Island and/or to contractors, grantees, or other recipients of the State of Rhode Island funds used to advance the interests of the State of Rhode Island, false and fraudulent claims for payment in connection with introducing non-cleared and otherwise adulterated and/or misbranded devices for sale in the State of Rhode Island.

369. The State of Rhode Island paid claims and incurred losses, and/or contractors, grantees, or other recipients of the State of Rhode Island funds used to advance the interests of the State of Rhode Island paid claims and incurred losses, as a result of Defendants' wrongful conduct.

370. By reason of such false and/or fraudulent claims, the State of Rhode Island has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

371. Pursuant to R.I. Gen. Laws § 9-1.1-3, the State of Rhode Island is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by the Defendants.

COUNT XXIX

Violation of the Tennessee Medicaid False Claims Act
(Tenn. Code Ann. § 71-5-181 *et seq.*)

372. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

373. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the State of Tennessee and/or to contractors, grantees, or other recipients of the State of Tennessee funds used to advance the interests of the State of Tennessee, false and fraudulent claims for payment in connection with introducing non-cleared and otherwise adulterated and/or misbranded devices for sale in the State of Tennessee.

374. The State of Tennessee paid claims and incurred losses, and/or contractors, grantees, or other recipients of the State of Tennessee funds used to advance the interests of the State of Tennessee paid claims and incurred losses, as a result of Defendants' wrongful conduct.

375. By reason of such false and/or fraudulent claims, the State of Tennessee has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

376. Pursuant to Tenn. Code § 71-5-182(a)(1), the State of Tennessee is entitled to three times the amount of actual damages plus the maximum penalty of $25,000 for each and every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by the Defendants.

COUNT XXX

Violation of the Texas Medicaid Fraud Prevention Law (Tex. Hum. Res. Code § 36.002 *et seq.*)

377. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

378. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the State of Texas and/or to contractors, grantees, or other recipients of the State of Texas funds used to advance the interests of the State of Texas, false and fraudulent claims for payment in connection with introducing non-cleared and otherwise adulterated and/or misbranded devices for sale in the State of Texas.

379. The State of Texas paid claims and incurred losses, and/or contractors, grantees, or other recipients of the State of Texas funds used to advance the interests of the State of Texas paid claims and incurred losses, as a result of Defendants' wrongful conduct.

380. By reason of such false and/or fraudulent claims, the State of Texas has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

381. Pursuant to Tex. Hum. Res. Code Ann. § 36.052, the State of Texas is entitled to two times the amount of actual damages plus the maximum penalty of $15,000 for each and every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by the Defendants.

COUNT XXXI

Violations of the Utah False Claims Act
(Utah Code Ann. § 26-20-1 *et seq.*)

382. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

383. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the State of Utah and/or to contractors, grantees, or other recipients of the State of Utah funds used to advance the interests of the State of Utah, false and fraudulent claims for payment in connection with introducing non-cleared and otherwise adulterated and/or misbranded devices for sale in the State of Utah.

384. The State of Utah paid claims and incurred losses, and/or contractors, grantees, or other recipients of the State of Utah funds used to advance the interests of the State of Utah paid claims and incurred losses, as a result of Defendants' wrongful conduct.

385. By reason of such false and/or fraudulent claims, the State of Utah has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

386. Pursuant to Utah Code Ann. § 26-20-9.5(2)(c), the State of Utah is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by the Defendants.

COUNT XXXII

Violation of the Virginia Fraud Against Taxpayers Act (Va. Code Ann. § 8.01-216.1 *et seq.*)

387. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

388. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the Commonwealth of Virginia and/or to contractors, grantees, or other recipients of the Commonwealth of Virginia funds used to advance the interests of the Commonwealth of Virginia, false and fraudulent claims for payment in connection with introducing non-cleared and otherwise adulterated and/or misbranded devices for sale in the Commonwealth of Virginia.

389. The Commonwealth of Virginia paid claims and incurred losses, and/or contractors, grantees, or other recipients of the Commonwealth of Virginia funds used to advance the interests of the Commonwealth of Virginia paid claims and incurred losses, as a result of Defendants' wrongful conduct.

390. By reason of such false and/or fraudulent claims, the Commonwealth of Virginia has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

391. Pursuant to Va. Code Ann. § 8.01-216.3(A), the Commonwealth of Virginia is entitled to three times the amount of actual damages plus the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by the Defendants.

COUNT XXXIII

Violation of the Washington State Medicaid Fraud False Claims Act (Rev. Code Wash. § 74.66.0005 *et seq.*)

392. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

393. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the State of Washington and/or to contractors, grantees, or other recipients of the State of Washington funds used to advance the interests of the State of Washington, false and fraudulent claims for payment in connection with introducing non-cleared and otherwise adulterated and/or misbranded devices for sale in the State of Washington.

394. The State of Washington paid claims and incurred losses, and/or contractors, grantees, or other recipients of the State of Washington funds used to advance the interests of the State of Washington paid claims and incurred losses, as a result of Defendants' wrongful conduct.

395. By reason of such false and/or fraudulent claims, the State of Washington has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

396. Pursuant to Rev. Code Wash. § 74.66.020(1), the State of Washington is entitled to three times the amount of actual damages plus the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by the Defendants.

COUNT XXXIV

Violation of the Wisconsin
False Claims for Medical Assistance Law
(Wisc. Stat. § 20.931 *et seq.*)

397. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

398. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the State of Wisconsin and/or to contractors, grantees, or other recipients of the State of Wisconsin funds used to advance the interests of the State of Wisconsin, false and fraudulent claims for payment in connection with introducing non-cleared and otherwise adulterated and/or misbranded devices for sale in the State of Wisconsin.

399. The State of Wisconsin paid claims and incurred losses, and/or contractors, grantees, or other recipients of the State of Wisconsin funds used to advance the interests of the State of Wisconsin paid claims and incurred losses, as a result of Defendants' wrongful conduct.

400. By reason of such false and/or fraudulent claims, the State of Wisconsin has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

401. Pursuant to Wisc. Stat. § 20.931(2), the State of Wisconsin is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by the Defendants.

WHEREFORE, Relator, on behalf of herself, and acting on behalf of, and in the name of, the Government, respectfully demands and prays that the Court enter judgment against Defendants as follows:

1. On Count I, Count II, and Count III, under the federal False Claims Act, a judgment in the amount of the damage to the Government, trebled as required by law, with civil penalties as required by law, together with all such further relief as may be just and proper;
2. On Count I, Count II, and Count III, under the federal False Claims Act, a judgment awarding Relator the maximum amount available under 31 U.S.C. § 3730(d) for bringing this action, namely twenty-five percent (25%) of the proceeds of the action by judgment or settlement if the Government intervenes in the matter (or pursues its claim through any alternative remedy available to the Government), or, alternatively, thirty-five percent (35%) of the proceeds of the action by judgment or settlement of the causes of action, if the Government declines to intervene;
3. On Count I, Count II, and Count III, under the federal False Claims Act, a judgment awarding Relator all reasonable expenses that were necessarily incurred in prosecution of this action, plus all reasonable attorneys' fees and costs, as provided by 31 U.S.C. § 3730(d);
4. On Counts IV through XXXIV, under the individual state false claims acts, a judgment in the amount of the damage to the individual state, doubled or trebled as permitted by each individual state statute, with civil penalties as required by each individual state statute, together with all such further relief as may be just and proper;

5. On Counts IV through XXXIV, a judgment awarding Relator the maximum amount available under under the individual state false claims acts for bringing this action, plus all reasonable expenses that were necessarily incurred in prosecution of this action, all reasonable attorneys' fees and costs, and all other remedies as provided under individual state false claims acts; and

6. Awarding such other relief for the Government and Relator as this Court deems just and proper.

Dated: July 2, 2014

Respectfully submitted,

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